

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA, *et al.*,  
*ex rel.* ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., *et al.*,

Defendants.

Civil Action No. 19-cv-12107-MEF-CLW

**SPECIAL MASTER ORDER**

**THIS MATTER** having come before the undersigned Special Master appointed by Order entered on March 18, 2024 (ECF No. 331); and the Order providing that the Special Master “shall oversee the schedule for completion of discovery, and all discovery disputes and motions related thereto, pursuant to procedures for practice that the Special Master may establish and modify as necessary”, *id.* at 2, ¶ 2; and the Special Master, in an effort to address and resolve the parties’ respective discovery disputes, having entered an Order on April 12, 2024 (ECF No. 337) setting deadlines for submissions relating to “[e]ach party’s first set of unresolved discovery issues” along with “[e]ach party’s second set of unresolved discovery issues”, *id.* at 1, ¶¶ 2-3; and the Special Master having considered the issues, arguments, and positions as to Relator’s efforts to depose Defendants’ senior executives who may be subject to protection under the “*Apex Doctrine*,” as set forth in: (1) Defendants’ submission of April 26, 2024 (ECF No. 341) (“Applications to Quash”); (2) Relator’s response of May 3, 2024 (ECF No. 344); (3) Relator’s letter of May 28, 2024 (ECF No. 356); (4) Defendants’ letter of May 31, 2024 (ECF Nos. 359, 360); and (5) Defendants’ letter of June 7, 2024 (ECF No. 361); and good cause appearing for the entry of this order

**IT IS** on this **19th** day of **June 2024 ORDERED** as follows:

1. Defendants’ Applications to Quash (ECF No. 341) are **GRANTED IN PART AND DENIED IN PART**.

2. The deposition notices as to Joaquin Duato and Robert Bazemore are hereby **QUASHED**.<sup>1</sup>

3. The deposition of Pearl Pugh is **ORDERED** to proceed. Within seven (7) days of this Order, the parties shall meet and confer as to a date, time, location, and mode for the deposition of Ms. Pugh.

### **SPECIAL MASTER DECISION**

The Special Master presumes the parties are well acquainted with the pertinent facts and procedural history of this matter. Before the Special Master is Defendants’ Applications to Quash Relator’s Deposition Notices to Joaquin Duato, Robert Bazemore, and Pearl Pugh. (ECF No. 341, p. 5.) Relator submitted a response, and the parties have each made at least one supplemental submission on these disputes. (ECF Nos. 344, 356, 359, 360, 361.)

#### **I. Legal Standard**

Pursuant to Rule 45, on timely motion, a court must quash or modify a subpoena that “subjects a person to an undue burden.” Fed.R.Civ.P. 45(d)(3)(A)(iv). Additionally, a court may, for good cause, issue a protective order to “protect a party or person from annoyance, embarrassment, oppression or undue burden or expense.” Fed.R.Civ.P. 26(c)(1).

Recognizing that depositions of high-level officers may severely burden the officers or the entities they represent, federal courts have developed the “apex doctrine,” an analytical framework

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<sup>1</sup> According to Defendants’ submission of April 26, 2024, Defendants ask the Special Master to “quash Relator’s notices to depose ... Duato[,] ... Bazemore[,] ... and Pugh[.]” (ECF No. 341, p. 5.) In the interest of clarity, any deposition notices *or* deposition subpoenas issued by Relator to Mr. Duato or Mr. Bazemore, are hereby quashed.

to guide courts in assessing whether to permit depositions of officers at the “apex” of corporations or other like entities. *See U.S. ex rel. Galmines v. Novartis Pharm. Corp.*, No. 06-cv-03213, 2015 WL 4973626, at \*1 (E.D. Pa. Aug. 20, 2015); *Harapeti v. CBS Television Stations Inc.*, No. 21-cv-15675, 2021 WL 8316391, at \*2 (D.N.J. Dec. 1, 2021). The “apex doctrine” applies when officers at the “top of the company” lack personal knowledge “about what is going on with the product, or its marketing, or its financing or really anything else that might be of interest to the plaintiffs, or the attorneys, or the jury, or the court.” *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 14-mc-00072, 2014 WL 3035791, at \*2 (E.D. Pa. July 1, 2014).

To assess whether the deposition of a high-level officer is appropriate, courts in this Circuit will consider two factors: “1) whether the executive has personal, superior, or unique knowledge on the relevant subject; and 2) whether the information can be obtained in a less burdensome way, such as through lower-level employees or other discovery methods.” *Mallory v. Wells Fargo Bank, N.A.*, No. 19-cv-00744, 2021 WL 2478473, at \*2 (M.D. Pa. June 17, 2021) (citation omitted); *In re Valeant Pharmaceuticals Int’l, Inc. Sec. Litig.*, No. 15-cv-07658, 2021 WL 3140030, at \*11 (D.N.J. July 7, 2021); *Ford Motor Co. v. Edgewood Props., Inc.*, No. 06-cv-01278, 2011 WL 2517133, at \*3 (D.N.J. June 23, 2011). This is “axiomatically, an extremely fact-sensitive determination.” *In re Lincoln Nat’l COI Litig.*, Nos. 16-cv-06605 and 17-cv-02592, 2019 WL 7581176, at \*2 (E.D. Pa. Dec. 5, 2019); *In re Valeant Pharmaceuticals*, 2021 WL 3140030, at \*11 (“A determination of these two factors involves a fact-sensitive analysis.”).

## **II. Special Master’s Decision**

### **a. Joaquin Duato, Johnson & Johnson CEO and Chairman of the Board.**

As to Joaquin Duato, the Special Master finds that Relator has not demonstrated that Mr. Duato possesses personal, superior, or unique knowledge relevant to the issues being litigated, and

also finds that the information sought from Mr. Duato should have been obtained from other sources or through other means. Mr. Duato is Johnson & Johnson's ("J&J") current CEO and Chair of the Board. He previously served as J&J's Executive Vice President and Worldwide Chairman, Pharmaceuticals, from 2011 to 2018.

The Special Master is not persuaded by Relator's assertion that because Mr. Duato personally presented to investors a PowerPoint of May 23, 2013, entitled "Pharmaceutical Commercial Overview" that related, in part, to Zytiga, he possesses superior or unique information on the prosecution of the '438 Patent. (ECF No. 344, p. 16.) Relator submits that he "reasonably believes" that Mr. Duato was closely involved in the preparation and revision of this presentation, and that he "presumably" had final sign-off on the document. However, the "apex doctrine" is a fact-sensitive inquiry and Relator's claims, based on "reasonable belie[f]" that Mr. Duato was closely involved in the preparation or revision of the presentation, or that Mr. Duato "presumably" had final sign off, are somewhat speculative. *See In re Lincoln Nat'l COI Litigation*, 2019 WL 7581176, at \*2; (ECF No. 344 p. 17).

Moreover, Relator's suspicions of Mr. Duato's involvement are refuted by Defendants' representations: Defendants have stated that the presentation was prepared by other employees (not Mr. Duato), that Zytiga was one of numerous topics included in the presentation, and, again, that the presentation has no bearing on the patent prosecution or patent counsel's decision on what information to submit to the USPTO. Indeed, Defendants strenuously maintain that Mr. Duato was not involved in the patent prosecution at issue in the litigation, and not involved in patent counsel's decision making regarding what information to submit to the USPTO. (ECF No. 341, p. 9.) Any personal knowledge Mr. Duato *does* have would not seem to be either unique or superior.

Furthermore, it seems Defendants have foregone the opportunity to question lower-level

employees with superior and unique knowledge of the presentation at issue, and how it was drafted, revised, and finalized. On June 7, 2024, Defendants submitted a letter to the Special Master noting that J&J Health Care Systems' Director of Specialty Pharmacy Capability, Christian Nebel, was involved in the drafting and revising of the slide deck presented by Mr. Duato, yet Relator scheduled and then canceled Mr. Nebel's deposition. Defendants claim that, under the "apex doctrine," Relator "must demonstrate the insufficiency of ... depositions of ... lower-level employees before obtaining a deposition of [the company] CEO." *Reif v. CAN*, 248 F.R.D. 448, 454 (E.D. Pa. 2008). Relator has not submitted a further response addressing or refuting Defendants' contentions in their June 7 letter.

In any case, the Special Master has reason to conclude that Relator should have examined other, less senior witnesses before seeking to depose Mr. Duato. Relator has not made a showing that the information relating to the understanding of what the presentation means, why the information in it was included, and why it presented the way it was cannot be obtained through less-intrusive means. The Special Master finds that Mr. Duato, having received the presentation after it had already gone through multiple levels of drafting and revision, does not possess personal, superior, or unique knowledge of why or how it was prepared or created. Moreover, Mr. Duato was not involved in the patent prosecution, and not involved in patent counsel's submission of information to the USPTO.

Accordingly, as to Mr. Duato, Defendants' Application to Quash is **GRANTED**.

b. Robert Bazemore, Former President, Janssen Biotech

As to Mr. Bazemore, the Special Master again finds that Relator has not demonstrated that Mr. Bazemore possesses personal, superior, or unique knowledge relevant to the issues being litigated, and also finds that information from Mr. Bazemore could have been obtained from other

sources or through other means. Mr. Bazemore was President of Janssen Biotech from 2011 to 2014, and served in that capacity at the time of the patent prosecution at issue, but left Janssen in 2014 to work for another company, from which he retired in 2021. (ECF No. 341, p. 10.)

Relator highlights the “likely importance” of Mr. Bazemore’s testimony citing his “regular presentations” concerning Zytiga before the application for the ’438 Patent was filed. (ECF No. 344 p. 9.) Relator points to no facts indicating that Mr. Bazemore was involved in the preparation or revision of the presentations, only that because he was the main presenter “[h]e therefore possesses personal knowledge” of a presentation that Relator “believes will play an important role at trial.” *Id.*

Defendants note that the presentations confirm that Mr. Bazemore was responsible for Janssen’s multiple product lines, that included Zytiga, but was not limited to Zytiga. Defendants represent that Mr. Bazemore was never involved in the “day-to-day decision-making” relating to Zytiga as Mr. Bazemore was in an executive role supervising multiple product lines, “running all of Janssen”. (ECF No. 341, p. 12.) They add that, like Mr. Duato, Mr. Bazemore was not involved in the patent prosecution or patent counsel’s decisions concerning what information to submit to the USPTO. Defendants maintain that, as Mr. Bazemore has no first-hand knowledge regarding the patent prosecution, he lacks personal, superior, or unique information related to Zytiga.

As the “apex doctrine” analysis is fact-sensitive, and Relator has not proffered any facts indicating that Mr. Bazemore possesses personal, superior, or unique knowledge with respect to the prosecution of the ’438 Patent, the Special Master finds that Mr. Bazemore is entitled to protection under the “apex doctrine.” In the Special Master’s view, the mere fact that Mr. Bazemore gave presentations on topics that included Zytiga does not refute Defendants’ representation that Mr. Bazemore was not involved in the patent prosecution, and not involved in

patent counsel's decisions on what information to submit to the USPTO. While Mr. Bazemore does have some connection to Zytiga by virtue of having presented on it, the Special Master does not find that Relator has established that he would have unique or superior knowledge.

Additionally, the Special Master finds that the "apex doctrine" does extend to former executives like Mr. Bazemore. Courts in this Circuit have routinely extended "apex" protection to former executives and officials. *See e.g., Harapeti*, 2021 WL 8316391, at \*2-3 (former CBS executive); *Galmines*, 2015 WL 4973626, at \*2-3 (former Novartis CEO); *Younes v. 7-Eleven, Inc.*, No. 13-3500, 2015 WL 12844446, at \*1, \*3 (D.N.J. Aug. 19, 2015) (former 7-Eleven Executive Vice President). The fact that Mr. Bazemore may no longer have the demanding schedule of a senior corporate executive does not make Mr. Bazemore ineligible for "apex doctrine" protection, and Relator has not persuasively established that Mr. Bazemore possesses personal, superior, or unique knowledge relating to the '438 Patent.

Accordingly, as to Mr. Bazemore, Defendants' Application to Quash is **GRANTED**.

- c. Pearl Pugh, Current Johnson & Johnson Vice President & Global Commercial Disease Area Stronghold Leader and Former Director of Marketing, Prostate Franchise.

As to Ms. Pugh, the Special Master finds that Relator has demonstrated that Ms. Pugh likely possesses personal, superior, or unique knowledge as it relates to the '438 Patent, and that the information from Ms. Pugh cannot be obtained from other sources or through other means. Ms. Pugh currently serves as J&J's Vice President and Global Commercial Disease Area Stronghold Leader for Rheumatology and Dermatology. She formerly served as J&J's Director of Marketing for the Prostate Franchise from 2015 to 2017.

Ms. Pugh is also listed in Defendant's Rule 26 disclosures, and Defendants produced documents from Ms. Pugh's custodial file from her tenure as Director of Marketing for the Prostate

Franchise. (ECF No. 341, p. 14.) Here, Relator points to the fact that Defendants produced 1,458 documents from Ms. Pugh's custodial file and "double that" when added with communications associated with her. (ECF No. 344, pp. 14-15.) The Special Master finds that Ms. Pugh almost certainly possesses personal, superior, and unique knowledge of these documents and communications during her tenure as Director of Marketing for the Prostate Franchise.

Defendants' argument that Ms. Pugh does not possess personal, superior, or unique knowledge because she was not hired by J&J until "nearly two years after the alleged fraud" is contradicted by their willingness to produce Ms. Pugh's replacement, Melissa Magee, who was hired at an even later time, and thus, who is even more removed from the prosecution of the '438 Patent. (*See* ECF No. 341, p. 14; ECF No. 344, p. 15.) The Special Master does not agree with Defendants that the information sought from Ms. Pugh can be obtained through Ms. Magee. While neither Ms. Magee nor Ms. Pugh held the role of Director of Marketing during the disputed patent prosecution in 2014 (ECF No. 341, p. 14), the Special Master believes Ms. Magee would not be able to comment on any relevant documents and communications from Ms. Pugh's tenure as Director of Marketing or otherwise produced from Ms. Pugh's custodial file. Rather, in all likelihood the information sought by Relator surrounding these documents and communications can best be elicited from Ms. Pugh herself. Her knowledge on this front is personal, superior, and unique.

Defendants maintain that in her current senior executive role Ms. Pugh's responsibilities do not relate to Zytiga, and that neither Ms. Pugh nor Ms. Magee have any personal knowledge of the alleged fraud at issue in the lawsuit. But Defendants have not denied that Ms. Pugh's prior responsibilities as Director of Marketing could have related to Zytiga. And, according to Relator, Defendants' disclosures note that Ms. Pugh had relevant subject matter knowledge relating to



“generic entry” to the extent the Commercial Success Argument implicates reasons for Zytiga’s competitive advantage and market share performance against potential generic competitors. (ECF No. 344, p. 15.)

Additionally, Defendants do not go so far as to represent that Ms. Pugh lacks superior or unique knowledge that is relevant to the claims and issues in the lawsuit aside from the alleged fraud.<sup>2</sup> In the Special Master’s view, merely because Ms. Pugh joined J&J after the prosecution of the patent at issue does not foreclose the possibility that she has relevant knowledge that cannot be obtained from other witnesses, including from Ms. Magee. Relator submits the compelling argument that because the ’438 Patent was not issued until September 2014, Defendants’ marketing efforts to maximize Zytiga’s success would have been relevant in 2015 when Ms. Pugh was employed at J&J as Director of Marketing. As an aside, even if Ms. Pugh’s successor, Ms. Magee, had unique knowledge, that alone does not preclude Ms. Pugh from likewise having unique knowledge of her own related to events and developments in 2015.

In a May 28, 2024, letter to the Special Master, Relator submitted deposition excerpts of two former employees of Defendants, Eric Harris and Victoria Vakiener. Although portions of the version submitted to the Special Master were redacted, the key statement from Relator in that submission was that “Ms. Vakiener confirmed that Ms. Pugh took over responsibility for this important function [*i.e.*, financial forecasting including “Loss of Exclusivity” assumptions] in 2014, and that Ms. Pugh would have the most direct knowledge of these critical assumptions from 2014 onward[.]” (ECF No. 356, p. 2.) Defendants’ response of May 31, 2024 (ECF No. 359) reiterates the timing of Ms. Pugh’s hire at J&J in 2015, which calls into question any testimony

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<sup>2</sup> Defendants’ letter of May 31, 2024 states that Ms. Pugh “lacks any personal, superior, or unique knowledge of the *alleged fraud* because she was not hired by J&J until March 2015[.]” (ECF No. 360, p. 1 (emphasis added).)

that Ms. Pugh had involvement in the forecasting role in 2014. Even if that were the case, the Special Master remains persuaded that Ms. Pugh has personal, unique, and superior knowledge at least for a portion of 2015 such that her examination should be permitted to go forward.

Accordingly, as to Ms. Pugh, Defendants' Application to Quash is **DENIED**. Within seven (7) days, the parties shall meet and confer as to a date, time, location, and mode for the deposition of Ms. Pugh.

### **III. Conclusion**

For the reasons set forth above, Defendants' Applications to Quash the Depositions of Joaquin Duato, Robert Bazemore, and Pearl Pugh are **GRANTED IN PART AND DENIED IN PART**, consistent with the rulings set forth above.

**IT IS SO ORDERED.**

Dated: June 19, 2024

*s/ Douglas E. Arpert*  
**DOUGLAS E. ARPert**  
**SPECIAL MASTER**